REMARKS

Claims 15-21 have been cancelled without prejudice. Applicants reserve the right to prosecute the cancelled subject-matter at a later date. Claims 12 and 13 have been amended. No new matter has been added. Support for the amendments can be found in originally filed claims 17-19.

Applicants thank the Examiner for withdrawing the previous objections to the specification, drawings and claims. Applicants also thank the Examiner for withdrawing the previous rejection of claims under 35 U.S.C. § 101, § 112 and § 102(b). Applicants further thank the Examiner for withdrawing the previous provisional rejection of claims 12 and 13.

Claims 12-13 and 22-23 are pending.

CLAIM REJECTIONS

Rejection of claims under 35 U.S.C. §112, first paragraph

The Examiner has maintained the previous rejection of claims 12, 13 and 15 under 35 U.S.C. § 112, first paragraph. See Office Action at p. 3. The Examiner has also rejected claims 16-23 under 35 U.S.C. § 112, first paragraph for lack of enablement. See Office Action at p. 4. In an effort to expedite prosecution and not in acquiescence to the rejection, Applicants have cancelled claims 15 and 16-21 thus rendering this rejection moot with respect to these claims. Claims 12 and 13 have been amended to incorporate the subject matter of claim 19.

The Examiner maintains that "the extremely broad scope of the instant claims, i.e., treatment/prevention of all autoimmune disorder constitutes merely an invitation to experiment without a reasonable expectation of success." See Office Action at p. 3. Applicants wish to point out that claims 12 and 13 are directed to a method for treating or preventing an autoimmune disease or an autoimmune disorder and a method for immunizing a subject against an autoimmune disease or an autoimmune disorder wherein the autoimmune disease or autoimmune disorder involves inflammation of the intima of a blood vessel. To further clarify this, Applicants have amended claims 12 and 13 to include an autoimmune disease or autoimmune disorder that is a vascular disorder selected from the group consisting of atheroma formation (otherwise known as arteriosclerosis), myointimal hyperplasia (natural or following

angioplasty), inflammatory and autoimmune thickening of the intima and/or muscular layer of blood vessels and myocarditis.

As previously explained, Example 10 within the specification describes a vascular disease model utilizing a rat angioplasty study. See p. 50, lines 10-17 of the specification. The model is based on an induced reduction of thickening of the intimal layers of the artery of rats. Id. As demonstrated in Example 10 (and in particular page 51 of the specification), the results for the intima reflect a reduction in post-angioplasty myointimal hyperplasia. Example 10 further demonstrates that *Gordonia bronchialis, Rhodococcus coprophilus* and *Tsukamurella inchonensis* were each effective in reducing the intima thickness in rats. Additionally, Example 11 on p. 52-54 of the specification describes the treatment of myocarditis in rats using *Tsukamurella inchonensis, Gordonia bronchialis, Rhodococcus rubber* and *Rhodococcus coprophilus*. Example 12 on p. 54-65 of the specification describes the treatment of post-coronary-angioplasty myointimal hyperplasia (MIH) using *Tsukamurella inchonensis*. Accordingly, Applicants have made a significant seminal finding that the use of the claimed organisms reduces inflammation of the intima of a blood vessel of a subject to which they are administered and this results in treatment or prevention of autoimmune disorders or diseases which involve inflammation of the intima of a blood vessel. See p. 54, line 22 to p. 65, line 10 of the specification.

Further, inflammatory responses at the sites of vascular injury play a key role in the progression of atherosclerotic vascular disease. See p. 58, lines 9-10 of the specification. Rupture of atherosclerotic plaques is the most common cause of sudden arterial occlusion leading to acute ischaemic syndromes such as myocardial infarction, stroke and peripheral artery occlusion. See p. 54, lines 27-29 of the specification. Thickening of the intima and a change of phenotype in the smooth muscle cells of the media together result in myointimal hyperplasia (MIH). See p. 55, lines 10-11 of the specification. Applicants have made the seminal finding that by repairing the intimal layer with minimal obstruction of blood flow (by reducing inflammatory response) using the administration of the organisms taught in the specification, treatment and/or prevention of autoimmune diseases and/or autoimmune disorders which involve inflammation of the intima of a blood vessel can be achieved. See Examples 10-12 of the specification. Further, the organisms from these different genera (i.e., *Gordonia, Rhodococcus*

and *Tsukamurella*) can be used to treat or prevent inflammatory responses of the intima of the blood vessel and thus treat or prevent autoimmune diseases and/or autoimmune disorders associated with such inflammatory responses. . See Examples 10, page 47, line 24 to page 51, line 20 of the specification. Notably, patients due to undergo percutaneous coronary intervention can be pretreated with compositions according the specification in order to reduce inflammatory response thus reducing (or preventing) the production of local myointimal hyperplasia and subsequent atheroma formation and re-stenosis of the artery. See p. 60, lines 21-24 of the specification.

Specific examples are provided in the specification as filed to show the treatment or prevention of myointimal hyperplasia (see Examples 10 and 12), and also myocarditis (see Example 11). In addition, Examples 10-12 of the specification also demonstrates the treatment of inflammatory thickening of at least the intima of the blood vessels. Finally, with respect to arteriosclerosis, there is sufficient guidance and direction in the specification for one of skill in the art to carry out the invention without undue experimentation.

As such, a person skilled in the art having been taught that a species from these different genera (i.e., *Gordonia, Rhodococcus* and *Tsukamurella*) were all effective in the reduction of intima thickness, would understand how to treat or prevent an autoimmune disease or an autoimmune disorder or immunize a subject against an autoimmune disease or an autoimmune disorder by administering an effective amount of a pharmaceutical composition and/or immune modulator composition that includes a whole cell of a bacterium from one or more of the genera *Rhodococcus, Gordonia, Nocardia, Dietzia, Tsukamurella* and *Nocardioides* to a subject wherein the autoimmune disease or autoimmune disorder involves inflammation of the intima of a blood vessel and is a vascular disorder selected from the group consisting of atheroma formation (otherwise known as arteriosclerosis), myointimal hyperplasia (natural or following angioplasty), inflammatory and autoimmune thickening of the intima and/or muscular layer of blood vessels and myocarditis

Accordingly, Applicants have informed and demonstrated to a person having ordinary skill in the art how to use the invention commensurate in scope with the claims. Accordingly, the specification adequately enables the claimed methods. Applicants respectfully request reconsideration and withdrawal of this rejection with respect to the remaining claims.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance.

Should any further fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

Date: 9-19-07

Harold H. Fox
Reg. No. 41,498

Customer Number: 27890
STEPTOE & JOHNSON LLP
1330 Connecticut Ave., NW
Washington, DC 20036
Tel: 202-429-3000
Fax: 202-429-3902